Contains No CBI

elf atochem

ELF ATOCHEM NORTH AMERICA, INC.
900 First Avenue, P.O. Box 1536
King of Prussia, PA 19406-0018

Tel: 215-337-6500

(A)

8EHQ-92-12611
8892001085O
INIT

October 12, 1992

CERTIFIED MAIL

RETURN RECEIPT REQUESTED

Document Processing Center (TS-790)
Office of Toxic Substances
U.S. Environmental Protection Agency
401 M St., S.W.
Washington, D.C. 20460

Attn: Section 8(e) Coordinator (CAP Agreement)

RE: Report Submitted Pursuant to the TSCA Section 8(e) Compliance Audit Program

CAP Identification Number: 8ECAP-0026

Dear Sir/Madam:

Pursuant to the Toxic Substances Control Act (TSCA) Section 8(e) Compliance Audit Program and the Agreement for TSCA Section 8(e) Compliance Audit Program (CAP Agreement) executed by Elf Atochem North America Inc. (Atochem) and Environmental Protection Agency (EPA), Atochem is submitting the enclosed oral LD_{50} determination study to the EPA. This study does not involve effects in humans.

Nothing in this letter or the enclosed study is considered confidential business information of Atochem.

The enclosed study provides information on the chemical tetraethyltin. Its exact chemical name is tetraethyl stannane and its CAS number is 597-64-8.

The title of the enclosed study is Acute Oral Toxicity Study in Rats With Tetraethyltin. The following is a summary of the adverse effects observed in this study.

Tetraethyltin (as a 1% v/v suspension in propylene glycol and corn oil) was administered by gavage to groups of five male albino rats at dosages ranging from 0.5 to 32 mg/kg. The oral LD_{50} was determined to be 6.25 mg/kg. Trembling, lack of muscular coordination and raspy respiration were noted at all dosages.

MM
2/9/95

Atochem previously submitted a TSCA Section 8(e) notice on tetraethyltin. The submission was made July 31, 1992; we have not been notified by EPA of the EPA Document Control Number for this submission.

Further questions regarding this submission may be directed to me at 215 337-6892.

Sincerely,

C.H. Farr, PhD, DABT
Manager, Product Safety
and Toxicology

Enclosures

FILED: CN 989-85

TR91-637

3

AME Associates
BIOLOGICAL RESEARCH

PRINCETON PIKE, P. O. BOX 57 ■ PRINCETON, N. J. 08540 ■ TEL.: (609) 924-9658

Project #20-178

T-444

Acute Oral Toxicity Study in Rats with Tetraethyltin

Conducted for

M & T Chemicals, Inc.
Rahway, New Jersey

Submitted by

AME Associates
Princeton, New Jersey

CAS: 597-64-1

A. M. E. ASSOCIATES P.O. BOX 57 PRINCETON, N. J. 08540

December 28, 1966

PROJECT #20-178

SPONSOR: M & T CHEMICALS, INC.

SUBJECT: Acute Oral Toxicity Study in Rats with M & T Chemicals, Inc., Tetraethyltin

OBJECTIVE

To study the acute oral toxicity in rats of M & T Chemicals, Inc., Tetraethyltin when administered (by means of a stomach tube) as a 1% v/v suspension in propylene glycol and corn oil.

MATERIAL

Tetraethyltin supplied by M & T Chemicals, Inc., for use in this study prepared as a 10% v/v suspension in propylene glycol and further diluted to yield a concentration of 10 mg/ml.

PROCEDURE

A group of twenty young, adult, male, albino rats of the Sprague-Dawley Strain weighing approximately 200-250 grams was employed for use in this study. The animals were divided into four subgroups of five animals each and fasted for twenty-four hours prior to intubation.

The experimental material was placed in a glass syringe and introduced through the esophagus into the stomach with a stainless steel catheter.

Animals on the same dosage level were then placed in a common cage with free access to food and water. The cages employed had wire mesh floors suspended above the droppings and were kept in temperature controlled rooms at 72° F ± 2° F. Light was furnished for eight out of every twenty-four hour period.

The animals were observed daily for a fourteen day period and deaths were recorded.

The LD_{50} was calculated using the Thompson Moving Average Method (Biometrics, September, 1952, Vol. 8, No. 3).

RESULTS

Dosage mg/kg	No. of Animals	Number and Day of Death														Total	
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	S*	D**
0.5	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	5	0
2	5	0	0	0	0	0	0	0	0	0	0	0	0	0	0	5	0
8	5	0	0	0	0	0	0	0	2	1	2	0	0	0	0	0	5
32	5	0	0	0	0	4	0	0	0	0	1	0	0	0	0	0	5

*Survivors

**Deaths

OBSERVATIONS

At 8 mg/kg and 32 mg/kg dosage levels, all animals exhibited extreme depression, excessive trembling, lack of muscular coordination, raspy respiration, diarrhea and salivation approximately two hours after intubation. Although deaths did not occur until day 5 at 32 mg/kg and day 9 at 8 mg/kg, all animals remained in the comatose state and showed the above symptoms until their deaths. The effects noted above were also evident in the 0.5 mg/kg and 2 mg/kg dosage level at a slightly lesser degree and all animals recovered fully by day 3.

CONCLUSION

The oral LD_{50} of M & T Chemicals, Inc., Tetraethyltin is 6.25 mg/kg with 95% confidence limits of 2 mg/kg and 8 mg/kg.

SUBMITTED BY Russell S. Edmonds

AME ASSOCIATES

Russell S. Edmonds, V.M.D.

President

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

C. H. Farr, PhD, DABT
Manager, Product Safety and Toxicology
Atochem North America, Inc.
900 First Avenue
P.O. Box 1536
King of Prussia, Pennsylvania 19406-0018

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

APR 18 1995

EPA acknowledges the receipt of information submitted by your organization under Section (e) of the Toxic Substances Control Act (TSCA). For your reference, copies of the first page(s) of your submission(s) are enclosed and display the TSCA §8(e) Document Control Number (e.g., 8EHQ-00-0000) assigned by EPA to your submission(s). Please cite the assigned 8(e) number when submitting follow-up or supplemental information and refer to the reverse side of this page for "EPA Information Requests".

All TSCA 8(e) submissions are placed in the public files unless confidentiality is claimed according to the procedures outlined in Part X of EPA's TSCA §8(e) policy statement (43 FR 11110, March 16, 1978). Confidential submissions received pursuant to the TSCA §8(e) Compliance Audit Program (CAP) should already contain information supporting confidentiality claims. This information is required and should be submitted if not done so previously. To substantiate claims, submit responses to the questions in the enclosure "Support Information for Confidentiality Claims". This same enclosure is used to support confidentiality claims for non-CAP submissions.

Please address any further correspondence with the Agency related to this TSCA 8(e) submission to:

Document Processing Center (7407)
Attn: TSCA Section 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Washington, D.C. 20460-0001

EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan

Terry R. O'Bryan
Risk Analysis Branch

Enclosure

12671A

Triage of 8(e) Submissions

Date sent to triage: APR 20 1995

NON-CAP (CAP)

Submission number: 12671A

TSCA Inventory: (Y) N D

Study type (circle appropriate):

Group 1 - Dick Clements (1 copy total)

ECO AQUATO

Group 2 - Ernie Falke (1 copy total)

(ATOX) SBTOX SEN (w/NEUR)

Group 3 - Elizabeth Margosches (1 copy each)

STOX CTOX EPI RTOX GTOX

STOX/ONCO CTOX/ONCO IMMUNO CYTO NEUR

Other (FATE, EXPO, MET, etc.): _____

Notes:

THIS IS THE ORIGINAL 8(e) SUBMISSION; PLEASE REFILE AFTER TRIAGE DATABASE ENTRY

For Contractor Use Only

entire document: (0) 1 2 **pages** 1, 2 **pages** 4, 5, 6

Notes:

Contractor reviewer : PRL **Date:** 4/3/95

CECATS\TRIAGE TRACKING DBASE ENTRY FORM

CECATS DATA:
Submission # 8EHQ- 1092 - 12671 SEQ. A

TYPE: (INT.) SUPP FLWP

SUBMITTER NAME: Elf Atochem North America, Inc.

SUB. DATE: 10/12/92 OTS DATE: 10/26/92 CSRAD DATE: 02/09/95

INFORMATION REQUESTED: FLWP DATE:
0501 NO INFO REQUESTED
0502 INFO REQUESTED (TECH)
0503 INFO REQUESTED (VOL ACTIONS)
0504 INFO REQUESTED (REPORTING RATIONALE)

DISPOSITION:
(0639) REFER TO CHEMICAL SCREENING
(0678) CAP NOTICE

VOLUNTARY ACTIONS:
(0401) NO ACTION REPORTED
0402 STUDIES PLANNED/UNDERWAY
0403 NOTIFICATION OF WORKERS/OTHERS
0404 LABEL/MSDS CHANGES
0405 PROCESS/HANDLING CHANGES
0406 APP./USE DISCONTINUED
0407 PRODUCTION DISCONTINUED
0408 CONFIDENTIAL

CHEMICAL NAME:

CAS#
597-64-8

INFORMATION TYPE:		P F C
0201	ONCO (HUMAN)	01 02 04
0202	ONCO (ANIMAL)	01 02 04
0203	CELL TRANS (IN VITRO)	01 02 04
0204	MUTA (IN VITRO)	01 02 04
0205	MUTA (IN VIVO)	01 02 04
0206	REPRO/TERATO (HUMAN)	01 02 04
0207	REPRO/TERATO (ANIMAL)	01 02 04
0208	NEURO (HUMAN)	01 02 04
(0209)	NEURO (ANIMAL)	01 (02) 04
0210	ACUTE TOX. (HUMAN)	01 02 04
0211	CHR. TOX. (HUMAN)	01 02 04
(0212)	ACUTE TOX. (ANIMAL)	01 (02) 04
0213	SUB ACUTE TOX (ANIMAL)	01 02 04
0214	SUB CHRONIC TOX (ANIMAL)	01 02 04
0215	CHRONIC TOX (ANIMAL)	01 02 04

INFORMATION TYPE:		P F C
0216	EPI/CLIN	01 02 04
0217	HUMAN EXPOS (PROD CONTAM)	01 02 04
0218	HUMAN EXPOS (ACCIDENTAL)	01 02 04
0219	HUMAN EXPOS (MONITORING)	01 02 04
0220	ECO/AQUA TOX	01 02 04
0221	ENV. OCCC/REL/FATE	01 02 04
0222	EMER INCI OF ENV CONTAM	01 02 04
0223	RESPONSE REQEST DELAY	01 02 04
0224	PROD/COMP/CHEM ID	01 02 04
0225	REPORTING RATIONALE	01 02 04
0226	CONFIDENTIAL	01 02 04
0227	ALLERG (HUMAN)	01 02 04
0228	ALLERG (ANIMAL)	01 02 04
0239	METAB/PHARMACO (ANIMAL)	01 02 04
0240	METAB/PHARMACO (HUMAN)	01 02 04

INFORMATION TYPE:		P F C
0241	IMMUNO (ANIMAL)	01 02 04
0242	IMMUNO (HUMAN)	01 02 04
0243	CHEM/PHYS PROP	01 02 04
0244	CLASTO (IN VITRO)	01 02 04
0245	CLASTO (ANIMAL)	01 02 04
0246	CLASTO (HUMAN)	01 02 04
0247	DNA DAM/REPAIR	01 02 04
0248	PROD/USE/PROC	01 02 04
0251	MSDS	01 02 04
0299	OTHER	01 02 04

TRIAGE DATA:	NON-CBI INVENTORY	ONGOING REVIEW	SPECIES	TOXICOLOGICAL CONCERN:	USE:	PRODUCTION:
	(YES)	YES (DROP/REFER)	RAT	LOW		
CAS SR	NO	NO (CONTINUE)		MED		
	UNKNOWN	REFER		(HIGH)		

COMMENTS

8(E)-12671A

H

ACUTE ORAL TOXICITY IN MALE RATS IS OF HIGH CONCERN BASED ON AN LD50 OF 6.25 MG/KG. DOSAGES (GAVAGE) AND MORTALITY DATA ARE AS FOLLOWS: 0.5 MG/KG (0/5); 2 MG/KG (0/5); 8 MG/KG (5/5); AND 32 MG/KG (5/5). CLINICAL SIGNS INCLUDED DEPRESSION, EXCESSIVE TREMBLING, MUSCULAR INCOORDINATION, SALIVATION, RASPY RESPIRATION, AND COMA.